



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 10, 2004

Mr. Steven G. Wigrizer
Wapner, Newman, Wigrizer and Brecher
115 South 21st Street
Philadelphia, PA 19103-4483

FILE COPY

Dear Mr. Wigrizer:

Your petition requesting the Food and Drug Administration to make a determination that the RLD, Pfizer Zithroma, azithromycin oral capsules, eq. 250 mg base, NDA 50-670, was not withdrawn from sale for reasons to safety or effectiveness, was received by this office on 05/07/04. It was assigned docket number 2004P-0220/CP 1 and it was filed on 05/07/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0220

ACK 1